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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/049,556 | 05/07/2002 | David Graham Little | RICE-006 | 7597 |
| 24353 | 7590 | 08/06/2004 | EXAMINER | |
| BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025 | | | CRIARES, THEODORE J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/049,556 | LITTLE, DAVID GRAHAM |
| | Examiner | Art Unit |
| | Theodore J. Criares | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 48-61,63-66 and 72-80 is/are pending in the application.
- 4a) Of the above claim(s) 54-61 and 75-77 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 48-53,63-66,72-74 and 78-80 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

CLAIMS 48-61, 63-66 AND 72-80 ARE
PRESENTED FOR EXAMINATION

Applicant's election without traverse of Group III, claims 48-53, 63-66 and 78-80 in the reply filed on May 14, 2004 is acknowledged.

Claims 54-61 and 75-77 are not examined with the elected group since the claims require a vibrating stimulus to be applied to the fractured bone which requires a separate classification to be searched. The addition of this feature to claims requires a separate search since it is classified in class 424, subclass 1.9. Therefore, these claims have acquired a separate status in the pharmaceutical art and an undue burden is placed on the examiner since these claims would require an additional search in the literature..

Claims 54-61 and 75-77 are withdrawn from consideration since they were previously restricted and the election was made without traverse.

Claims 48-53, 63-66, 72-74 and 78-80 have been examined.

.DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48 and 63 the independent claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Ke et al. (6,352,970).

Applicant's claims are drawn to the treatment of bone fracture comprising administering a bisphosphonate and promoting new bone formation, respectively. The claims are to be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319; 13 USPQ 2d 1320 (Fed. Cir. 1989). The claims recite the term "comprising" and thus additional agents can be present in the treatment of a fracture.

Ke et al teaches the use of Zoledronate, the specific bisphosphonate of claim 73 at column 5, lines 22-34 is capable of treating bone fractures. The difference between the reference and applicant's claims is that the reference is combining the bisphosphonate with a leptin or fragment thereof. However, the skilled artisan would have been motivated to use applicant's claimed known bisphosphonate, since the reference teaches a bisphosphonate in combination treat bone fractures at column 26, lines 24-40 will promote healing.

The mode, dosage as a single dose, site, time and regiments of administration of claims 49-53, 64-66, 72, 74 and 78-80 are taught at column 16, lines 13-64, column 17, lines 1-25 and lines 40-45. At column 18, lines 18, lines 30-45 it is taught that the administration can be done in a regiment to the site as determined by the patients needs.

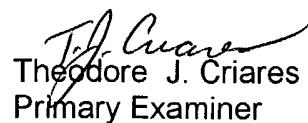
The reference also teaches administration may be transdermal, intravenous or oral.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a *prima facie* case of obviousness. is presented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares
Primary Examiner

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